

Remarks**Rejection of Claim 13 Under 35 U.S.C. §112, second paragraph**

Claim 13 stands rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Applicants respectfully traverse the rejection.

The Office asserts that claim 13 is vague because it appears to be for detection of an analyte. A claim is definite when those skilled in the art would understand what is claimed when the claim is read in light of the specification. *See, Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986). Claim 13 recites that “[t]he self-referencing colorimetric resonant optical biosensor of claim 9, wherein the one or more specific binding substances are bound to their specific binding partners.” Claim 9 recites that “one or more specific binding substances [are] immobilized on a first portion of the colorimetric resonant optical biosensor of each liquid-holding vessel.” Therefore, claim 13 relates to the situation where a self-referencing colorimetric resonant optical biosensor has specific binding partners bound to the one or more specific binding substances, which are immobilized on the biosensor. This condition would occur, for example, after a test sample was applied to the biosensor.

One of skill in the art, given the specification, would understand what is claimed. Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 9, 10, 11, 12, and 14 Under 35 U.S.C. §103(a)

Claims 9, 10, 11, 12, and 14 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Pat. No. 5,738,825 (the ‘825 patent) in view of U.S. Pat. No. 4,992,385 (the ‘385 patent). Applicants respectfully traverse the rejection.

Under *Graham v. John Deere* (383 U.S. 1 (1966)) factual inquiries to be made in determining obviousness are: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art. To establish a *prima facie* case of obviousness three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the references, when combined must teach or suggest all the claim limitations. *See, In re*

Merck & Co., 800 F.2d 1091, 1097 (Fed Cir. 1986); *In re Rouffett*, 149 F.3d 1350, 1357 (Fed. Cir. 1998); MPEP §2143.

Initially, the cited references do not teach each and every element of the claims. The ‘825 and ‘385 patents do not teach or suggest a colorimetric resonant optical biosensor surface.

Next, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings.

The ‘825 patent does not teach or suggest that each individual liquid-holding vessel has two separate surfaces: 1) a reaction surface (comprising one or more specific binding substances immobilized on the biosensor surface of the liquid-holding vessel) and 2) a reference surface (having no specific binding substances immobilized on the biosensor surface of the liquid-holding vessel). Rather, the ‘825 patent teaches that:

In a further aspect this invention provides a method for the automated analysis of samples using an optical biosensor, the method comprising filling the wells of a detection cell as defined above with a carrier fluid; transporting the detection cell to a position to cooperate with a reading unit as defined above; monitoring the out-coupled light from each well and recording it to provide a reference; transporting the detection cell to a pipetting station and pipetting a sample into each well; transporting the detection cell back to the reading unit and directing light onto the diffraction grating means in the detection cell; monitoring the out-coupled light from each well; and comparing the results obtained to the reference. *See*, col. 3, lines 39-50.

The ‘825 patent does not teach or suggest that each individual liquid-holding vessel or well could be separated into separate testing surfaces, which would have greatly reduced the amount of time, labor, and reagents required to complete these assays. If incorporation of standard regions into each well was obvious or feasible it seems that the inventors of the ‘825 patent would have incorporated such regions in order to eliminate the labor and time intensive steps of taking reference measurements of the wells as described above. Furthermore, the ‘825 patent does not provide any methodology for scanning and obtaining readings from a reference surface and a reaction surface in a single liquid-holding vessel or well.

The ‘385 patent suggests that droplets of solution (*see*, col. 6, lines 10-16) may be applied to a biosensor surface. The ‘385 patent also suggests that the droplets may be applied to a discrete test region and a standard (untreated) region of one biosensor. *See*, col. 3, lines 10-18.

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The biosensor of the '385 patent, however, do not contain individual liquid-holding vessels. Therefore, at least two test droplets would be applied to a generally flat surface of a biosensor in each of the two "distinct" regions (or the entire biosensor surface would have to be washed over with the test solution; however, the '385 patent teaches that droplets are used). The '385 patent does not teach or suggest 1) a reaction surface and 2) a reference surface wherein only one application of the test solution would need to be applied *because* both the reaction surfaces and reference surfaces are present in only one liquid-holding vessel. Therefore, the combination of the '825 and '385 patents does not teach or suggest the self-referencing colorimetric resonant optical biosensor of the instant invention.

Finally, the combination of the '825 patent and the '385 patent do not provide for a reasonable expectation of success. Neither patent teaches or suggests how both a reference surface and a reaction surface would be read in each individual liquid-holding vessel.

The combination of the '825 patent and '385 patent does not render the instant invention obvious. Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

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